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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,479	08/06/2001	John Macdonough	13413-002001	1521
26161	7590	03/16/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			PRATT, HELEN F	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,479

Applicant(s)

MACDONOUGH ET AL.

Examiner

Helen F. Pratt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giles, Jr. (6,025,363).

Giles, Jr. disclose a composition containing a kavalactone, which can be Kawain, yangonin and the other claimed kavalactones (col. 3, lines 23-30). The composition can contain from 50 to 350 mg kava root extract, which contains about 2-50% by weight kavalactones, which is within the claimed amount. (col. 4, lines 66-68). No alcohol is seen in the composition. The composition is considered to be a beverage because the composition may be in an oral liquid (col. 4, lines 39-41). Stabilizers can be carboxymethyl cellulose, methylcellulose, and sodium alginate, as in claims 2, 7 and 8. Claims 1-4, 7 and 8 differ from the reference in the particular amount of the beverage. However, it would have been within the skill of the ordinary worker to use particular amounts of the active ingredient in particular amounts of liquid depending on what effects the beverage was to have on a person. Therefore, it would have been obvious to use the kavalactone in particular amounts of beverage and to use stabilizers for their known functions.

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Claim 5 further requires higher amounts from 500 mg-1000 mg of the active ingredient, kavalactone in the beverage. The reference discloses that the composition can contain from 2-50% kavalactones (col. 6, lines 60-65). As the function of the kavalactone is known, which is to promote anti-anxiety and relaxing benefits, it would have been obvious to use more kavalactones, i. e. 50 % of the weight of the composition depending on the weight of the composition, which would encompasses the claimed range.

Claim 6 further requires particular amounts of the stabilizer blend. However, as the function of stabilizers is well known, it would have been obvious to use particular amounts to stabilize the ingredients, particularly as the references disclose the use of stabilizers with kavalactones.

Claims 9-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giles, Jr. as applied to claims 1-8 above, and further in view of Meadows 6,238,722.

Claim 9 requires a preservative, claim 10 an antioxidant, claim 11, an anti-microbial, claims 12 and 13, a natural sweetener, which can be sugar. Giles, Jr. discloses that flavoring agents, and aromatic agents can be used (col. 6, lines 1-5) in the composition. No ingredients are seen at present that actually require an antioxidant, therefore, nothing critical is seen in its use. In addition, these are common ingredients routinely used in beverages. Sweeteners such as fructose or other sugar-based sweeteners can be used in a beverage containing kavalactones as disclosed by Meadows (col. 3, lines 19-35). Therefore, it would have been obvious to use known ingredients to make the claimed beverage.

Claim 15 further requires a flavoring agent, claim 16 a natural flavoring agent and claim 17 particular flavorants, and claims 18 and 19, particular flavorants or fruit concentrate. Meadows discloses that it is known to use chocolate with kavalactones and acids. Natural acids are generally found in fruit juices, which are a good source of ascorbic acid as in the reference to Meadows. Nothing new is seen in using a fruit concentrate instead of acids in the claimed composition, which also contains natural acids. The particular flavoring agents of claim 17 are well known spices except for the grapefruit seed. Attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in the fact situation of the instant case, and wherein the Court stated on page 234 as follows:

This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected, and useful function. *In re Benjamin D. White*, 17 C.C.P.A (Patents) 956, 39 F.2d 974, 5 USPQ 267; *In re Mason et al.*, 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221. Therefore, it would have been obvious to use known ingredients in the claimed composition for their known function.

Claim 20 further requires water in the beverage. Meadows discloses water (col. 4, lines 30-35). Therefore, it would have been obvious to use water in to make a beverage as shown by Meadows in the composition of Giles because Giles also discloses an oral liquid.

Claim 21 further requires ingredients, which have been discussed above, claims 22-24 particular amounts of ingredients. However, as the ingredients are well known ingredients in making beverages, it would have been obvious to use particular amounts to make the claimed beverage, especially in view of In re Levin above.

Claim 25 requires that the beverage is a health beverage, claim 26, that it induces relaxation, claim 27, that it reduces stress, and claim 28 that synthetic active kavalactones are used. The beverage of the combined references is known to reduce anxiety (col. 1, lines 10-14 of Meadows) and calming and relaxing states as disclosed by Giles, Jr. (abstract). Certainly, the beverage of the combined references could be considered a health beverage, as it has healthy ingredients in it. Synthetic active kavalactones are disclosed by Giles, Jr. (col. 3, lines 32-40). Therefore, it would have been obvious to make a beverage, which has the claimed effects and which also uses synthetic active kavalactones as disclosed above.

Claims 29 and 30 are to the method of making the beverage. No alcohol is seen in the compositions of the references. The particular composition has been disclosed by the above composition. The ingredients are seen to have been combined as claimed (col. 3, lines 19-35 of Meadows). Therefore, it would have been obvious to combine the ingredients of the above references to make a beverage.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 703-308-1978. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HP 3-8-04.


HELEN PRATT
PRIMARY EXAMINER